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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,448	09/22/1999	BARRY J. BYRNE	4300.012100	8377

7590 03/26/2002

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/404,448	BYRNE ET AL.
	Examiner	Art Unit
	Gerald Leffers	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 41-62 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 41-62 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 9/22/99 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.

- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

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### **DETAILED ACTION**

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

The time period for suspension following entry of the RCE that was approved in Paper No. 16 has passed. In a telephonic interview on January 17, 2002 applicants' representative requested some additional time to confer with his clients about making a biological deposit to over come rejection of some claims under 35 U.S.C. 112, first paragraph. Applicants have now had over six months from the time of suspension of the instant application (9/4/02) to investigate the possibility of making a deposit of the claimed biological material. Prosecution is hereby reopened in this application. Receipt is acknowledged of an amendment, filed 9/4/02 as Paper No. 15, in which claims were amended (41-60) and in which new claims were added (claims 61-62). Any rejection of record in the previous office action (Paper No. 12) not addressed in this action has been withdrawn. New rejections are made in this action under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Claims 41-62 are pending in this application.

#### *Information Disclosure Statement*

Receipt is acknowledged of an information disclosure statement (IDS), filed 9/4/01 as Paper No. 17. The signed and initialed PTO Form 1449 has been mailed along with this action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for reasons of record in Paper No. 12 against claims 41-45. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive.**

To summarize the rejection, these claims are drawn towards a specific recombinant HSV-1/AAV hybrid virus (rHSV d27.1rc) which is encompassed by the definition of biological material set forth in 37 C.F.R 1.801. Because it is apparent that this biological material is essential for practicing the claim invention, it must be obtainable by a reproducible method set forth in the specification or otherwise known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

***Response to Arguments***

It is noted that applicants' amendments to claims 41-45 in Paper No. 15 obviate the rejection made towards these claims. However, new claims 61-62 are now directed towards the rHSV d27.1rc strain previously recited in claims 41-45. Applicants' response in Paper No. 15 to rejection of claims for lack of enablement with regard to rHSV d27.1rc essentially states that

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applicants are investigating the necessary procedures for fulfilling the requirement of a biological deposit of the viral strain.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59, 61-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

Claim 59 is vague and indefinite in that it depends from itself. It would be remedial to amend the language of claim 59 to indicate dependency on different claim.

Claims 61-62 are vague and indefinite in that the metes and bounds of the term “(ATCC XXXX)” are unclear. It would be remedial to amend the claim language to include an actual accession number.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46, 56-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al (B1; see the entire document). **This rejection is maintained for reasons of record**

**in Paper No. 12. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive for reasons given in the Response to Arguments below.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 56-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al in view of Muzyezka (V; see the entire document). **This rejection is maintained for reasons of record in Paper No. 12. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive for reasons given in the Response to Arguments below.**

Claims 41-48 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (B1) and Glorioso et al (B; see the entire reference). **This rejection is maintained for reasons of record in Paper No. 12. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive for reasons given in the Response to Arguments below.**

Claims 41-48 and 50-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (B1) and Rice et al (U; see the entire reference). **This rejection is maintained for reasons of record in Paper No. 12. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive for reasons given in the Response to Arguments below.**

Claims 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (B1) and Efstathiou et al (A; see the entire patent). **This rejection is maintained for reasons of record in Paper No. 12.. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive for reasons given in the Response to Arguments below.**

***Response to Arguments***

Applicant's arguments filed in Paper No. 15 in response to rejections made in Paper No. 12 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) have been fully considered but they are not persuasive. The response essentially states that after a requested interview with the examiner a more complete response will be filed.

***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

AGS  
ggl  
March 25, 2002

DAVID GUZO  
PRIMARY EXAMINER  
